

## RESPONSE TO OFFICE ACTION

### A. Status of the Application

The Action notes that the previous RCE and submission under 37 C.F.R. §1.114 have been entered. Claims 1, 2, 4-10 and 13 are currently pending in the case and under consideration and are presented herein for reconsideration.

### B. Specification Objection

The Action objects to the specification at page 13 as including a drawing. Applicants traverse, but note in the interest of expedited prosecution that the specification has been amended to delete Scheme 1 and that Scheme 1 has been presented as new FIG. 1 herewith. A legend for FIG. 1 has been added to the specification. The objection is therefore now moot and removal thereof is thus respectfully requested.

### C. Rejection Under 35 U.S.C. §112, First Paragraph – Written Description

The Action rejects claims 1, 2, 4-10 and 13 as lacking an adequate written description. In particular, the Action asserts a failure to adequately describe non-transgenic genes conferring glyphosate and glufosinate tolerance. In response, Applicants respectfully note that the current claims are directed to transgenes conferring glyphosate and glufosinate tolerance and thus the rejection is moot. Removal of the rejection is thus respectfully requested.

### D. Rejection Under 35 U.S.C. §112, First Paragraph – Enablement

The Action rejects claims 1, 3, 4-10 and 13 as lacking enablement under 35 U.S.C. §112, first paragraph. In particular, the Action asserts a failure to enable non-transgenic genes

conferring glyphosate and glufosinate tolerance. In response, Applicants respectfully note that the current claims are directed to transgenes conferring glyphosate and glufosinate tolerance and thus the rejection is moot. Removal of the rejection is thus respectfully requested.

**E. Rejection Under 35 U.S.C. §11, Second Paragraph**

The Action states that claim 13 is indefinite for use of the term “commercially acceptable grain yield.” Specifically, it is asserted that this phrase is relative and not defined by the specification, and thus it is not clear what level of grain yield is commercially acceptable. Applicants respectfully traverse as the term is defined by the specification and is definite. In particular, paragraph 0034 of the specification defines “commercially acceptable” as follows:

Commercially acceptable--The term commercially acceptable means a soybean variety having a grain yield of greater than 35 bushels per acre over at least two years and 10 environments.

Therefore, a commercially acceptable grain yield is a yield of greater than 35 bushels per acre over at least two years and 10 environments. This definition is fully definite to those of skill in the art given these criteria. The claim is therefore definite under the second paragraph of §112 and removal of the rejection is thus respectfully requested.

**F. Rejection Under 35 U.S.C. §103**

The Action rejects claims 1, 2, 4-10 and 13 as obvious under 35 U.S.C. §103(a) over Padgett *et al.* (*Crop Science* 35:1451-1461, 1995) in view of Russell *et al.* (EPO 0430511A1) further in view of Hacker *et al.* (U.S. Patent No. 5,599,769). In particular, it is stated that Padgett *et al.* teach soybean plants having tolerance to glyphosate and Russell *et al.* teach soybean plants having tolerance to glutamine synthetase inhibitors, and that Hacker *et al.* teach

herbicidal compounds containing more than one herbicide, including glyphosate and glufosinate, thus providing the motivation to cross the plant of Russell with the plant of Padgett to arrive at the claimed plants.

Applicants respectfully traverse as the prior art was completely devoid of a reasonable expectation of obtaining the claimed invention as of the filing date. Specifically, absolutely no basis has been provided for concluding why one of skill in the art would have expected that transgenes conferring tolerance to both glyphosate and glufosinate could be expressed in a single soybean plant as of the filing date. In fact, Applicants below provide substantial evidence affirmatively demonstrating why such an expectation was lacking. As the reasonable expectation of success must specifically be shown in the art as of the filing date, the rejection must be withdrawn as set forth below. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976).

### **1. The Newly Cited Hacker *et al.* Reference Establishes Non-Obviousness**

In addition to the evidence previously submitted by Applicants, the Hacker *et al.* reference (U.S. 5,599,769, issued Feb. 4, 1997) newly cited by the Action also establishes the non-obviousness of the claimed invention. Hacker *et al.* was cited in the Action as teaching “herbicidal compounds containing more than one herbicide, including both glufosinate and glyphosate” and thus motivating those of skill in the art to combine genes conferring tolerance to these herbicides to “take full advantage of the synergistic effects of using multiple herbicides on crop fields.” Action at p.7. However, the synergistic effects briefly alluded to in fact demonstrate the non-obviousness of the claims. For example, Hacker *et al.* explain that “*Surprisingly*, some herbicidal active substances have now been found in biological tests which, when applied together with glufosinate-ammonium or glyphosate, result in pronounced

*synergistically increased effects.”* (emphasis added), Hacker *et al.* at Col. 1, l. 33-36. Hacker *et al.* further explain that:

If the active substance combinations are applied post-emergence to the green parts of the plant, ***growth stops dramatically*** very soon after the treatment, and the weed plants remain in the growth stage of the time of application, or die more or less rapidly after a certain period of time. The weeds are controlled very effectively in this manner. When used for controlling weeds in plantations, competition by the weeds, which is harmful to the crop plants, is eliminated in a sustained manner by using the novel compositions according to the invention.

(emphasis added) *Id.* at Col. 3, l.58-67. Hacker *et al.* also state the following:

For example, using the active substance combinations according to the invention, a herbicidal action is achieved which ***exceeds what would have been expected*** as an additive action of the individual components. Such increased effects permit the dosage rates of the individual active substances to be reduced substantially. While the dosage rates are comparable, the weed-grass weed ***spectrum controlled is much broader*** by virtue of the synergistic effects. At the same time, properties which are of the utmost importance in practical use are considerably improved in the case of most combinations. These include, for example, the ***speed of action, the long-term action,*** the flexibility upon use, etc. This permits comprehensive, rapid, sustained and economical control of weeds and grass weeds. Such properties are therefore economically progressive because they offer considerable advantages to the user in practical weed control by allowing him to control weeds more economically or more rapidly or in a more sustained manner, therefore obtaining higher yields in a stand of crop plants.

(emphasis added) *Id.* at Col. 4, l.58-67.

Hacker *et al.* therefore specifically demonstrate that the activity of the combination of glyphosate and glufosinate is ***not additive*** and is in fact unpredictable. The herbicidal activity of the two herbicides together is shown to be substantially increased and more lethal to plants relative to either herbicide alone. It therefore follows that obtaining tolerance to both herbicides is also not additive and is unpredictable. The teachings cited in the Action pertaining to glufosinate or glyphosate tolerance alone therefore cannot be directly applied to the current claims as was done in the action. The findings of tolerance to glyphosate and glufosinate by the Applicants as shown in the working examples is therefore particularly surprising. In contrast, all

of the cited art relates to tolerance to either herbicide individually. This evidence alone therefore more than adequately shows non-obviousness.

## **2. The Byrum Declaration Establishes Non-Obviousness**

The previously submitted Declaration of Dr. Joseph R. Byrum explained in specific detail why one of skill in the art would have been without any reasonable expectation of success in arriving at the invention. Dr. Byrum explained, for example, that a soybean variety had never been developed having more than one herbicide resistance transgene combined in a single soybean plant prior to the current invention. It was further explained that the expression of herbicide resistance transgenes requires manipulation of complex metabolic pathways of plant cells. As soybean plants do not naturally exhibit herbicide tolerance, the results of a given modification are unpredictable.

Transgene expression further causes complex pleiotropic effects that can vary depending upon factors such as the location of insertion of the transgene in a genome, the transgene being expressed, the genotype of the host soybean plant, and the regulatory elements and any enhancers used to express the transgene. The expression of enzymes not normally present in a plant also creates a “metabolic drag” reducing energy from the diversion of resources to the expression of the transgene. Dr. Byrum thus concluded that the absence of pleiotropic or other effects preventing the combination of these traits to arrive at the claimed invention would have been speculation prior to the studies in the application and thus one of skill in the art would have been without any reasonable expectation in arriving at the claimed invention as of the filing date.

Byrum Declaration, p.4.

### **3. Summary**

In sum, those of skill in the art could not have predicted prior to the invention how herbicide resistance transgenes conferring glyphosate and glufosinate tolerance would interact. Regardless of the description of plants resistant to one herbicide, the fact remains that one of skill in the art would not have known how these genes would interact as of the filing date. This is demonstrated by the unpredictable and synergistic effects observed when herbicides are combined as shown by Hacker *et al.*, the complete absence of a herbicide resistance trait in wild type soybeans at all, the complex biochemical pathways that must be modified to obtain herbicide tolerance, and the unpredictable and non-additive manner in which genes interact in plants.

Findings of fact and conclusions of law by the U.S. Patent and Trademark Office must be made in accordance with the Administrative Procedure Act (APA), 5 U.S.C. § 706(A), (E), 1994. *Dickinson v. Zurko*, 527 U.S. 150, 158 (1999). The APA requires that findings of fact by the Board of Patent Appeals and Interferences must be supported by “substantial evidence” on the record. *In re Gartside*, 203 F.3d 1305, 1315 (Fed. Cir. 2000). It therefore follows that the Examiner must present “substantial evidence” within the record showing why the foregoing evidence is incorrect. Here, Applicants have affirmatively demonstrated that such an evidentiary basis is lacking and no basis for concluding otherwise has been provided. Removal of the rejection under 35 U.S.C. § 103 is thus respectfully requested.

**G. Conclusion**

In light of the foregoing, applicants submit that all claims are in condition for allowance, and an early indication to that effect is earnestly solicited. The examiner is invited to contact the undersigned (512)536-3085 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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